NOV 2 1 2005

K052702

Exhibit E **510(k) SUMMARY - Misonix Inc. FS-1000-RF Bipolar Forceps Accessory**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

1. **Submitter's Identification**

Submitter's Name:	MISONIX INCORPORATED
Address:	1938 New Highway, Farmingdale, NY 11735
Telephone Number:	516-694-9555
Contact Person:	Ronald R. Manna
Date Prepared:	August 22, 2005

2. **Name of Device**

Proprietary Name:	Misonix Inc. FS-1000-RF Bipolar Forceps Accessory
Common/Usual Name:	Electrosurgical cutting and coagulation device and accessories
Product Code:	GEI
Classification:	Class II

3. **Predicate Device Information**

Predicate Devices	Boston Surgical Products Inc. Disposable Bipolar Coagulating Forceps K942710 Olsen Electrosurgical Inc. Teflon Coated Electrodes for Electrosurgical Handles K913108 Guenter Bissinger Medizintechnik GmbH Claris Non Stick Bipolar Forceps K051429

4. **Device Description** Metal and plastic construction that approximates a tweezer assembly. Includes provision for connection to the output of a standard bipolar electrosurgical generator. Also includes provision for mechanical attachment to an ultrasonic surgical

aspirator. There is no energy interaction between the ultrasound unit and the electrosurgery unit.

5. **Intended Use:**

The Misonix Inc. FS-1000-RF Bipolar Forceps Accessory is indicated for use in bipolar procedures to grasp, manipulate, coagulate and/or transect tissues in the following specialities:

Neurosurgery
Plastic and Reconstructive Surgery
General Surgery

6. **Comparison to Predicate Device**

FS-1000-RF Bipolar Forceps Accessory is similar in design, material and operating parameters to the Boston Surgical Products Inc. Disposable Bipolar Coagulating Forceps, the Olsen Electrosurgical Inc. Teflon Coated Electrodes for Electrosurgical Handles and the Guenter Bissinger Medizintechnik GmbH Claris Non Stick Bipolar Forceps.

All devices utilize two electrodes made of metal material, usually stainless steel or titanium. A coating of titanium oxide is used on the Misonix FS-1000-RF forceps accessory to minimize tissue adhesion. Predicates use other coatings such as Teflon to accomplish the same effect.

The prongs of the forceps are held together at the proximal end by plastic assemblies which both provide a spring action to either hold the forceps open or closed without operator intervention. Nylon coatings insulate the prongs so that the operator is not touching the RF energized metal, providing a measure of safety.

7. **Safety and Performance Data**

The Misonix Inc. FS-1000-RF Bipolar Forceps Accessory have been designed and tested to pass the following Voluntary Standards:

UL 2601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1 Medical Electrical Equipment, Part 1: General Requirements for Safety
EN 60601-1-2:2001 Electromagnetic Compatibility
EN 60601-2-2 Medical Electrical Equipment, Part 2: Particular Requirements for the safety of high frequency surgical equipment
FCC Part 18 EMC Requirements

7. **Software Validation** This device does not contain software.

8. **Sterilization Validations** Validation statements are contained in Exhibit J.

9. **Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Note: Forceps are passive devices. Testing was done while attached to standard electrosurgical generator. Testing confirmed that forceps did not alter expected output characteristics of any generator tested.

Life Tests
Input Power Measurements
EMI Tests
Dielectric Tests on Mains Circuits
Patient Current Leakage and Patient Sink Current Measurements
Power Line Ground Leakage Measurements
Dielectric Tests on Patient Circuits
RF Cautery Life Tests
Dielectric Tests with RF Cautery Unit Attached
RF Cautery Unit Ouput Power Tests
Temperature testing with tips closed for prolonged period of time

9. **In Vitro Tests Performed**

Testing of bipolar effect on animal tissue (bench top)
Temperature testing of forceps during prolonged bench testing
Surgeon assisted trial on animal tissue (bench top) for clinician feedback

10. **Conclusions**

Based upon a review of the published literature and its internal testing, Misonix Inc. can state that the use of the FS-1000-RF Bipolar Forceps Accessory for grasping, manipulating, coagulation and transecting tissue is safe and efficacious. We can also state that the FS-1000-RF Bipolar Forceps Accessory is substantially equivalent in this regard to the Boston Surgical Products Inc. Disposable Bipolar Coagulating Forceps, the Olsen Electrosurgical

Inc. Teflon Coated Electrodes for Electrosurgical Handles and the Guenter Bissinger Medizintechnik GmbH Claris Non Stick Bipolar Forceps.

Based upon the engineering and in vitro testing experiences outlined herein, the device poses no new issues of safety or efficacy for coagulating and transecting tissue.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 1 2005

Ronald R. Manna
Vice President Regulatory Affairs
Misonix, Inc.
1938 New Highway
Farmingdale, New York 11735

Re: K052702
Trade/Device Name: Misonix Inc. FS-1000-RF Bipolar Forceps Accessory
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: September 23, 2005
Received: September 28, 2005

Dear Mr. Manna:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman
for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K052702

Device Name: Misonix Inc. FS-1000-RF Bipolar Forceps Accessory

Indications for Use:

The Misonix Inc. FS-1000-RF Bipolar Forceps Accessory is indicated for use in bipolar procedures to grasp, manipulate, coagulate and/or transect tissues in the following specialities:

Neurosurgery
Plastic and Reconstructive Surgery
General Surgery

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052702